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Safety assessment of the process 'Morssinkhof Plastics', used to recycle high-density polyethylene and polypropylene crates for use as food contact materials

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Abstract

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) deals with the safety evaluation of the recycling process 'Morssinkhof Plastics', EU register No RECYC0142. The input consists of crates, boxes, trays, pallets and containers, hereafter termed 'crates', used in food contact, made of high-density polyethylene (HDPE) or polypropylene (PP). It comprises unused damaged crates, prewashed used crates and parts of crates originating from closed and controlled product loops. The process separates crates by material type and food type (fruit, vegetables and prepacked meat vs unpacked meat). Flakes from recycled HDPE or PP are produced that will be used by customers to manufacture new crates for food contact. The Panel considered that the management system put in place to ensure compliance of the origin of the input with Commission Regulation (EC) No 282/2008 and to provide full traceability from input to final product is the critical process step. It concluded that the input of the process 'Morssinkhof Plastics' originates from product loops which are in closed and controlled chains designed to ensure that only materials and articles which have been intended for food contact are used and that any contamination can be ruled out when run under the conditions described by the applicant. The recycling process 'Morssinkhof Plastics' is, therefore, able to produce recycled HDPE and PP suitable for manufacturing HDPE and PP crates intended to be used in contact with dry food, fruits and vegetables, prepacked and unpacked meat. The use of regrind from 'external' recyclers only based on private agreements, does not give reassurance to fall under the scope of Art. 4 c (i) of Commission Regulation (EC) No 282/2008 and is excluded from the present evaluation.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Recycled plastic materials and articles shall only be placed on the market if they contain recycled plastic obtained from an authorised recycling process. Before a recycling process is authorised, EFSA's opinion on its safety is required. This procedure has been established in Article 5 of Regulation (EC) No 282/2008¹ of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of Regulation (EC) No 1935/2004² of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the Member States Competent Authorities which transmit the applications to the European Food Safety Authority (EFSA) for evaluation.

In this case, EFSA received, from the Ministry of Health, Welfare and Sport, The Netherlands, an application for evaluation of the recycling process 'Morssinkhof Plastics', EU register No RECYC0142. The request has been registered in EFSA's register of received questions under the number EFSA-Q-2016-00486. The dossier was submitted on behalf of Morssinkhof Plastics Lichtenvoorde B.V, The Netherlands.

According to Article 5 of Regulation (EC) No 282/2008 of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods, EFSA is required to carry out risk assessments on the risks originating from the migration of substances from recycled food contact plastic materials and articles into food and deliver a scientific opinion on the recycling process examined.

According to Article 4 of Regulation (EC) No 282/2008, EFSA will evaluate whether it has been demonstrated in a challenge test, or by other appropriate scientific evidence, that the recycling process 'Morssinkhof Plastics' is able to reduce any contamination of the plastic input to a concentration that does not pose a risk to human health. The high density polyethylene (HDPE) and polypropylene (PP) materials and articles used as input of the process as well as the conditions of use of the recycled plastic make part of this evaluation.

2. Data and methodologies

2.1. Data

The applicant has submitted a dossier following the 'EFSA guidelines for the submission of an application for the safety evaluation of a recycling process to produce recycled plastics intended to be used for the manufacture of materials and articles in contact with food, prior to its authorisation' (EFSA, 2008). Applications shall be submitted in accordance with Article 5 of the Regulation (EC) No 282/2008.

The following information on the recycling process was provided by the applicant and used for the evaluation:

- General information:
 - general description,
 - existing authorisations.
- Specific information:
 - recycling process,
 - characterisation of the input,
 - characterisation of the recycled plastic,
 - intended application in contact with food,
 - compliance with the relevant provisions on food contact materials and articles,
 - process analysis and evaluation,
 - operating parameters.

¹ Regulation (EC) No 282/2008 of the European parliament and of the council of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006. OJ L 86, 28.3.2008, p. 9–18.

² Regulation (EC) No 1935/2004 of the European parliament and of the council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

2.2. Methodologies

The principles followed for the evaluation are described here. The risks associated to the use of recycled plastic materials and articles in contact with food come from the possible migration of chemicals into the food in amounts that would endanger human health. The quality of the input, the efficiency of the recycling process to remove contaminants as well as the intended use of the recycled plastic are crucial points for the risk assessment (see guidelines on recycling plastics; EFSA, 2008).

In 2011, EFSA published an opinion on the safety evaluation of a mechanical recycling process to produce recycled polyethylene terephthalate (PET) (EFSA CEF Panel, 2011). The principle presented in this opinion is applicable to any plastic. However, some of the criteria used in the evaluation procedure are specific to PET and, therefore, cannot be applied directly to PP or HDPE.

The assessment was conducted in line with the principles described in the EFSA Guidance on transparency in the scientific aspects of risk assessment (EFSA, 2009) and considering the relevant guidance from the EFSA Scientific Committee.

3. Assessment

3.1. General information

According to the applicant, the recycling process 'Morssinkhof Plastics' is intended to recycle precleaned crates, parts of crates and possibly unused damaged food contact HDPE and PP crates to produce recycled HDPE or PP flakes. These flakes may be blended with virgin HDPE or PP, or be used up to 100% to manufacture recycled HDPE and PP crates intended to be used for long-term storage of dry food, fruits and vegetables and for storage of prepacked meat and unpacked meat at room temperature or below.

3.2. Description of the Morssinkhof Plastics process

3.2.1. General description

According to the applicant, the input of the recycling process can be precleaned crates, parts of crates or (unused) damaged crates, the meaning of crates including boxes, trays, pallets and containers that have been used in food contact. Crates are from (a) pooling organisations, where crates are used and recycled in closed and controlled loops, or (b) unwashed HDPE or PP regrind from crates from closed and controlled loops, produced by approved external recyclers.

The process includes the following steps:

- 1) Damaged unused HDPE and PP crates and crates at the end of the service life (e.g. because of damages), precleaned by the pooling organisations (input), are received for grinding into flakes. Before grinding, administrative checks on the origin of crates (closed and controlled loops) and visual inspections to sort out contaminated crates are performed. The HDPE and PP feedstocks from crates are ground separately. The input is also separated according to the type of supplier (pooling organisation or external recycler) and according to the previous use (A: fruits, vegetables and prepacked meat; B: unpacked meat). Metal parts are removed before and after grinding, and the regrind is dedusted.
- 2) The regrind, produced on-site or provided by external recyclers, is washed with freshwater in order to remove potential adhering contamination (paper, dust, fines). Remaining paper parts and plastic are removed by centrifugation. Small particles are removed through a sieve. The regrind is then dried with hot air [REDACTED].

Dry regrind is packed in new big bags for storage and transport to the end customers. Recycled flakes are intended to be used to manufacture new recycled HDPE and PP crates by injection moulding, with or without blending with virgin HDPE or PP.

3.2.2. Characterisation of the input

According to the applicant, the input material for the recycling process 'Morssinkhof Plastics' consists of unused damaged prewashed HDPE or PP crates and damaged prewashed HDPE and PP

crates or parts of them, that have been used in contact with food in a closed loop of growers, distributors and retailers for packaging, transport and storage and display of dry food, fruits and vegetables as well as prepacked and unpacked meat.

The crates are collected by the pooling organisations and transported to washing lines. For this washing process, water, detergents and air are used. The crates are cleaned according to hygienic standards of the food industry to be used again. Damaged crates or crates that are not usable any more, but suitable for recycling, are recycled by 'Morssinkhof Plastics' Lichtenvoorde B.V. According to the applicant, the reusable crates are made of HDPE or PP originally produced in compliance with the Commission Regulation (EU) No 10/2011 relating to plastic materials and articles intended to come into contact with foodstuffs.

Regrind supplied by approved external recyclers may also be used, accompanied with documentation required by Morssinkhof.

According to the applicant, the existing internal quality assurance system ensures that the input originates exclusively from closed and controlled loops and provides full traceability of the material processed within its premises.

3.2.3. Characterisation of the output

The following technical specifications for the HDPE and PP flakes have been established by the applicant: melt flow index, colour, regrind size, density, heavy metals and residual moisture.

Up to 100% recycled HDPE and PP flakes may be used by the end customers to manufacture new recycled HDPE or PP crates (after injection moulding).

4. Data on comparative testing of one time and five time recycled material

The effect of repeated grinding and injection moulding of HDPE and PP crates on the formation of degradation products was assessed following a protocol proposed by Coulier et al. (2007). Through this protocol, migration tests by total immersion of specimens made of one and five times recycled HDPE crates (ground and injection-moulded) were compared. Three replicated tests were performed.

The following parameters were tested:

- [REDACTED]
- Specific migrations of several substances (monomers and additives) with a specific migration limit (SML) in the Regulation EU No 10/2011, used in the manufacturing of the resins or in the original crates. Worst-case simulants were selected for each substance and different analytical techniques were used.

[REDACTED]

- Screening methods have been applied to investigate differences between the two samples:
 - Release of volatile substances in the headspace was screened by solid phase micro extraction coupled with mass spectrometry (SPME-GC/MS).
 - Migration of semivolatile substances [REDACTED], screened by (GC/MS),
 - Migration of non-volatile substances up to 1,000 Da into isooctane [REDACTED] and 20% ethanol [REDACTED], investigated using gel permeation chromatography coupled with refractive index detection (GPC/RI).

There was no significant difference in the overall migrations between the five times recycled and the one time recycled material.

Specific migration of substances with a SML into their worst-case simulants was found well below the SML in all cases and in most cases below the limit of quantification. No differences in migration for the substances in the five times recycled vs one time recycled material was observed.

No new volatile compounds were detected in the five times recycled compared to the one time recycled material.

The semivolatile substances that were slightly increased in the five times recycled material have been identified as far as possible and consisted of degradation products of the polymer, such as long-chain hydrocarbons and an alkanolic acid.

No non-volatiles below 1,000 Da were detected in the 20% ethanol simulant, and there was no significant difference between one time and five times recycled material in the isooctane extracts.

5. Compliance with the relevant provisions on food contact materials and articles

According to the applicant, the prewashed reusable HDPE and PP crates used as input materials for the recycling process are made of plastic that complies with Commission Regulation (EU) No 10/2011. As demonstrated by comparative testing, there are only minor differences between one time and five times reprocessed HDPE material, used as worst-case scenario, representative also of PP.

6. Process analysis and evaluation by the applicant

The applicant presented a process analysis in which the following points are made:

The recycling process is managed by a quality assurance scheme in which continuous control is performed, ensuring that contamination and the risks involved with those contaminations are negligible.

To demonstrate the potential risk of incidental contamination during use, a risk calculation was made using a worst case scenario, showing very low levels of potential contamination of the crates.

7. Discussion

The data presented by the applicant allow identifying the process, its input, output and intended uses of final articles. The recycling process uses input material supplied by pooling organisations belonging to product loops of growers, distribution centres, retailers, cleaners. Within the loop, the crates are used for long term storage of whole fruits and vegetables, prepacked and unpacked meat at cooled or at room temperature. At the end of their service life (e.g. because of damages), precleaned crates (input) are recycled. In the recycling process, the crates are ground into flakes, which are subsequently washed and dried. These flakes can be used up to 100% by the end customers to manufacture new recycled crates by injection moulding.

The applicant also performs washing and drying of regrind (accompanied by documentation required by Morssinkhof) supplied by external approved recyclers.

Considering the high temperatures used in the further processing of the flakes (injection moulding by the customers to produce new crates), the possibility of contamination by microorganisms can be discounted. Therefore, this evaluation focuses on the chemical safety of the final product.

Based on the description of the process, the Panel considers that this process is within the scope of Art. 4 c(i) of the Regulation (EC) No 282/2008, when the plastic input is supplied by a pooling organisation belonging to a product loop in a closed and controlled chain for which EFSA has published a positive opinion. Accordingly, the use of regrind from 'external' recyclers only based on private agreements, i.e. without a positive EFSA opinion, does not give reassurance to fall under the scope of Art. 4 c (i) and is excluded from the present evaluation.

The Panel considered that the grinding of the crates and the washing of the recycle, under the conditions described for the applicant, are not of safety concern.

The Panel considered the management of the input material as a critical process step.

The traceability system of 'Morssinkhof Plastics' introduces a number of identifiers for labelling crates and recording the type of plastic, the type of supplier and the original use of the input entering the system. During the process, reference and batch numbers are used for the grinding and washing steps. The Panel considers that this system must achieve and keep complete separation of:

- HDPE from PP material;
- input from each pooling organisation;
- material for contact with fruits, vegetables and packed meat from material for contact with unpacked meat due to different food contact.

The recycled HDPE and PP flakes are characterised by technical specifications, mainly related to the required mechanical properties of the material. The effect of repeated grinding and injection moulding of HDPE crates on the formation and migration of degradation products, additives, monomers and oligomers has been assessed by comparison of the migration of these substances from one time and five times reprocessed HDPE material. The tests demonstrated negligible differences, which the Panel considered not to give rise to a safety concern for the intended use of the final product.

8. Conclusions

The Panel considered that the recycling process 'Morssinkhof Plastics' ensures that only materials and articles intended for food contact are used and that any contamination can be ruled out, provided that the inputs originate from product loops which are in closed and controlled chains for which EFSA has published a positive opinion. The recycling process 'Morssinkhof Plastics' is, therefore, able to produce recycled HDPE and PP suitable for manufacturing HDPE and PP crates intended to be used in long term contact at room temperature or below. The system should achieve and keep complete separation of materials for contact with fruits, vegetables and packed meat from material for contact with unpacked meat. The use of regrind from 'external' recyclers only based on private agreements, does not give reassurance to fall under the scope of Art. 4 c (i) of Regulation (EC) 282/2008 and is excluded from the present evaluation.

9. Recommendations

The Panel recommends that it should be verified periodically, as part of the good manufacturing practice (GMP) in the meaning of the Regulation (EC) No 2023/2006, that the input originates from materials and articles that have been manufactured in accordance with the EU legislation on food contact materials and articles (Regulation (EC) No 282/2008, Art. 4b). Specifications for input (unused damaged crates, cleaned crates used within a product loop which is in a closed and controlled chain) as well as separate processing of material intended for different food contact uses (dry foods, fruits, vegetables and packed meat versus unpacked meat), should be kept under control to ensure that the process is run under the evaluated conditions.

Documentation provided to EFSA

- 1) Dossier 'Morssinkhof Plastics'. November 2016. Submitted by 'Morssinkhof Plastics' Lichtenvoorde B.V., the Netherlands.
- 2) Additional data for the dossier 'Morssinkhof Plastics'. May 2017. Submitted by 'Morssinkhof Plastics' Lichtenvoorde B.V., the Netherlands.

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Abbreviations

CEF	Food Contact Materials, Enzymes, Flavourings and Processing Aids
GC/MS	gas chromatography coupled to mass spectrometry
GMP	good manufacturing practice
GPC/RI	gel permeation chromatography coupled with a refractive index detector
HDPE	high-density polyethylene

[REDACTED]

PET	poly(ethylene terephthalate)
PP	polypropylene
SML	specific migration limit
SPME	solid phase microextraction

[REDACTED]